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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

PATHEON SOFTGELS INC. and BIONPHARMA INC.,	
Plaintiffs,	**C.A. No. _____**
v.	
PURACAP PHARMACEUTICAL LLC,	**JURY DEMAND**
Defendant.	*Electronically Filed*

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Patheon Softgels Inc. ("PSI"), and Bionpharma Inc. ("Bionpharma") (collectively with PSI, "Plaintiffs"), for their complaint against PuraCap Pharmaceutical LLC ("Defendant" or "PuraCap"), hereby allege as follows:

NATURE OF THE ACTION

1. This is a civil action for infringement of United States Patent Nos. 9,693,978 ("the '978 patent"), 9,693,979 ("the '979 patent"), 10,022,344 ("the '344 patent"), and 10,028,925 ("the

'925 patent") (collectively, the "Asserted Patents"). This action is based upon the Patent Laws of the United States, 35 U.S.C. § 1 *et seq*.

THE PARTIES

2. Plaintiff PSI is a Delaware corporation having a principal place of business at 4125 Premier Drive, High Point, North Carolina 27265.

3. Plaintiff Bionpharma is a Delaware corporation having a principal place of business at 600 Alexander Road, Suite 2-4B, Princeton, New Jersey 08540.

4. On information and belief, Defendant PuraCap is a New Jersey corporation having a principal place of business at 20 Kingsbridge Road, Piscataway, New Jersey 08854.

JURISDICTION AND VENUE

5. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

6. This Court has personal jurisdiction over the Defendant by virtue of the fact that, *inter alia,* the Defendant has committed, or aided, abetted, induced, contributed to, and/or participated in the commission of, tortious acts of patent infringement that have led to foreseeable harm and injury to Plaintiffs in New Jersey. This Court has personal jurisdiction over the Defendant for the additional reasons set forth below and for other reasons that will be presented to the Court if such personal jurisdiction is challenged.

7. This Court has personal jurisdiction over Defendant PuraCap by virtue of, *inter alia*, the fact that PuraCap is a New Jersey corporation.

8. Venue is proper for PuraCap under 28 U.S.C. § 1400(b) because PuraCap resides in New Jersey. Further, venue is proper in the Trenton Vicinage of the District Court of New Jersey because, upon information and belief, PuraCap has a regular and established place of business in Piscataway, N.J., a township within Middlesex County, and has committed tortious

acts of patent infringement there.

BACKGROUND

9. On July 4, 2017, the '978 patent, titled "Solvent System for Enhancing the Solubility of Pharmaceutical Agents," was duly and legally issued by the United States Patent and Trademark Office ("USPTO"). PSI is the sole owner of the '978 patent. Bionpharma is the exclusive licensee of the '978 patent. A copy of the '978 patent is attached hereto as Exhibit A.

10. On July 4, 2017, the '979 patent, titled "Liquid Dosage Forms of Sodium Naproxen," was duly and legally issued by the USPTO. PSI is the sole owner of the '979 patent. Bionpharma is the exclusive licensee of the '979 patent. A copy of the '979 patent is attached hereto as Exhibit B.

11. On July 17, 2018, the '344 patent, titled "Liquid Dosage Forms of Sodium Naproxen" was duly and legally issued by the USPTO. Since the issuance of the '344 patent, PSI has been, and continues to be, the '344 patent's sole owner. Bionpharma is the exclusive licensee of the '344 patent. A copy of the '344 patent is attached hereto as Exhibit C.

12. On July 24, 2018, the '925 patent, titled "Liquid Dosage Forms of Sodium Naproxen" was duly and legally issued by the USPTO. Since the issuance of the '925 patent, PSI has been, and continues to be, the '925 patent's sole owner. Bionpharma is the exclusive licensee of the '925 patent. A copy of the '925 patent is attached hereto as Exhibit D.

13. Bionpharma holds New Drug Application ("NDA") No. 021920 for 220 mg Naproxen Sodium (EQ 200 mg Base) Over-the-Counter ("OTC") capsules.

14. The '978, '979, '344, and '925 patents are listed in the United States Food and Drug Administration ("FDA") publication "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") for 220 mg Naproxen Sodium (EQ 200 mg Base) OTC capsules for NDA No. 021920.

15. Upon information and belief, PuraCap submitted ANDA No. 208363 to the FDA under § 505 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). Upon information and belief, ANDA No. 208363 sought FDA approval for the commercial manufacture, use, and sale of a generic version of Plaintiffs' 220 mg Naproxen Sodium (EQ 200 mg Base) OTC drug product ("the PuraCap Generic Product"). Upon information and belief, ANDA No. 208363 references Bionpharma's NDA No. 021920. Upon information and belief, the FDA approved ANDA No. 208363 on March 15, 2018. A copy of the Orange Book listing for ANDA No. 208363 is attached hereto as Exhibit E.

16. Upon information and belief, PuraCap uses, offers for sale, and/or sells within the United States, and/or imports into the United States, the PuraCap Generic Product, including in this Judicial District. PuraCap further induces and contributes to such conduct.

17. Upon information and belief, PuraCap has made and continues to make the PuraCap Generic Product available for sale and/or use by others in the United States, *inter alia*, through selling to retailers in the United States directly or through an intermediary supplier.

18. Upon information and belief, retailers, including at least Target Corporation, are currently selling the PuraCap Generic Product in the United States including in this Judicial District. Upon information and belief, these capsules are manufactured in China and imported into the United States. Photographs showing a sample of the packaging for the PuraCap Generic Product (referred to herein as "the PuraCap Generic Product Packaging"), marked with the designation "NDC 11673-748-40,"[1] are attached as Exhibit F and Exhibit G. This NDC

[1] "NDC" stands for "National Drug Code." The NDC is a unique 10-digit, 3-segment number that serves as a universal product identifier for all human nonprescription (OTC) and prescription medication packages and inserts in the United States. The first of the three segments of the NDC identifies the "labeler" (manufacturer, repackager, or distributer). The second

designation corresponds to the PuraCap Generic Product, as shown in an excerpt of the National Drug Code Directory, attached hereto as Exhibit H. Exhibit H also states this product is marketed pursuant to "ANDA208363," which, as stated above and in Exhibit E, is the ANDA owned by defendant PuraCap.

19. Upon information and belief, the PuraCap Generic Product includes naproxen sodium (*see* Exhibit F) as well as additional, inactive ingredients: FD&C blue #1, gelatin, glycerin, lactic acid, lecithin, light mineral oil, n-butyl alcohol, polyethylene glycol, povidone, propylene glycol, purified water, shellac glaze, sorbitol sorbitan solution, titanium dioxide, and white ink. *See* Exhibit G.

20. Upon information and belief, the amount of lactic acid in the PuraCap Generic Product is about 5% by weight of the capsule fill material.

21. The PuraCap Generic Product Packaging states that the product is a "pain reliever/fever reducer (NSAID)" (Exhibit F) and lists uses for the product including "temporarily relieves minor aches and pains due to: minor pain of arthritis, backache, headache, the common cold, muscular aches, menstrual cramps, toothache," and "temporarily reduces fever," and directs adults and children 12 years and older to "take 1 capsule every 8 to 12 hours while symptoms last." *See* Exhibit G.

22. Upon information and belief, multiple additional retailers have submitted labels to the National Drug Code Directory for the PuraCap Generic Product. Retailers including at least CVS Pharmacy, Safeway, Inc., Target Corporation, and Walgreens have registered labels for the PuraCap Generic Product, as listed in the National Drug Code Directory. PuraCap has also

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segment identifies the specific strength, dosage form (*i.e.*, capsule, tablet, liquid) and formulation of a drug for a specific manufacturer. Finally, the third segment is the package code, which identifies package sizes and types.

registered a label for the PuraCap Generic Product, as listed in the National Drug Code Directory. Upon information and belief, these labels are consistent with the PuraCap Generic Product Packaging. Excerpts of the National Drug Code Directory listings for Naproxen Sodium Liquid Filled Capsules are attached hereto as Exhibit I.

Count I – Patent Infringement by PuraCap

23. Plaintiffs repeat and reallege paragraphs 1-22 above as if fully set forth herein.

24. PuraCap's use, offer for sale, and/or sale within the United States, and/or importation into the United States, of the PuraCap Generic Product constitutes infringement of the Asserted Patents under 35 U.S.C. § 271(a), (b), (c), and/or (g) because, *inter alia*, the PuraCap Generic Product, the methods of making the PuraCap Generic Product, and the methods of using the PuraCap Generic Product – *e.g.*, by doctors, pharmacists, healthcare providers, and patients according to the PuraCap Generic Product Packaging – meet each and every claim element of at least Claims 1, 4, 5, 6, 8, 10, 13, 14, 15, 17, 22, 23, 24, 25, 26, and 27 of the '978 patent, Claims 1 and 7 of the '979 patent, Claims 1, 2, 3, 7, 9, 10, 11, 13, 17, 19, and 20 of the '344 patent, and Claims 1, 2, and 8 of the '925 patent, either literally or under the doctrine of equivalents.

25. On information and belief, PuraCap was aware of the '978 patent and the '979 patent at least since these patents were listed in the Orange Book on or about November 13, 2017. Further, upon information and belief, PuraCap was aware of the '344 and '925 patents at least since these patents were listed in the Orange Book on or about July 25, 2018. On information and belief, the PuraCap Generic Product Packaging induces others – *e.g.*, doctors, pharmacists, healthcare providers, and patients – to infringe the '978 patent, the '979 patent, the '344 patent, and the '925 patent, and PuraCap possesses the specific intent to induce and encourage others to infringe those patents.

26. On information and belief, PuraCap knows or should know that its use, offer for sale, and/or sale within the United States, and/or importation into the United States, of the PuraCap Generic Product induces and contributes to infringement of the Asserted Patents. On information and belief, PuraCap has caused and continues to cause third parties to directly infringe the Asserted Patents through purchase and use of the PuraCap Generic Product.

27. On information and belief, PuraCap has knowledge that by making the PuraCap Generic Product available for sale and/or use by others – *e.g.*, by doctors, pharmacists, healthcare providers, and patients during the shelf life of the PuraCap Generic Product – before expiration of the '978 patent, the '979 patent, the '344 patent, and the '925 patent, such activities result in the sale and/or use of a product especially made for an infringing use. Upon information and belief, PuraCap has knowledge of such infringing use and also knows that the PuraCap Generic Product is not a staple article or commodity of commerce suitable for substantial noninfringing use, but rather is especially made and/or adapted for use in the direct infringement of the '978 patent, the '979 patent, the '344 patent, and the '925 patent. On information and belief, such conduct by PuraCap was intended to, and actually resulted in, direct infringement by its customers, either literally or under the doctrine of equivalents.

28. PuraCap's actions render this an exceptional case under 35 U.S.C. § 285.

29. Plaintiffs will be irreparably harmed by PuraCap's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment as follows:

A. That PuraCap has infringed the Asserted Patents;

B. That PuraCap, its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, be preliminarily and permanently enjoined from

commercially manufacturing, using, offering for sale, or selling in the United States, or importing into the United States, the PuraCap Generic Product, and any other product that infringes or induces or contributes to the infringement of the Asserted Patents, prior to the expiration date of the last to expire of those patents, including any extensions or exclusivities;

C. That Plaintiffs be awarded monetary relief sufficient to compensate Plaintiffs for damages resulting from PuraCap's infringement of the Asserted Patents, and that such monetary relief be awarded to Plaintiffs with prejudgment interest;

D. That Plaintiffs be awarded the attorneys' fees, costs, and expenses that they incur prosecuting this action under 35 U.S.C. § 285 and;

E. That Plaintiffs be awarded such other and further relief as this Court deems just and proper.

Dated: October 5, 2018

By: *s/Liza M. Walsh*

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RULE 11.2 CERTIFICATION

We hereby certify that, to the best of our knowledge, the following related actions and proceedings are pending:

1. *Patheon Softgels Inc., Bionpharma Inc., and Bionpharma Healthcare LLC v. Apotex Inc. and Apotex Corp.,* Case No. 3:17-cv-13819-MAS-LHG (D.N.J. December 29, 2017) (Consolidated).[2]

Dated: October 5, 2018

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[2] *Patheon Softgels Inc., Bionpharma Inc., and Bionpharma Healthcare LLC v. Ohm Laboratories, Inc.,* Case No. 3:18-cv-00486-MAS-LHG (D.N.J. Jan. 12, 2018) was consolidated with Case No. 3:17-cv-13819-MAS-LHG.

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RULE 201.1 CERTIFICATION

We hereby certify that the above-captioned matter is not subject to compulsory arbitration in that the Plaintiffs seek, *inter alia*, injunctive relief.

Dated: October 5, 2018

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